

## Aortic Valve Repair in Congenital Heart Surgery using CardioCel® patch

Kretzschmar J.<sup>2</sup>, Nordmeyer S.<sup>1,3</sup>, Murin P.<sup>2</sup>, Schulz A.<sup>2</sup>, Danne F.<sup>1</sup>, Nordmeyer J.<sup>1</sup>, Sumbadze D.<sup>1</sup>, Schmitt K. R. L.<sup>1</sup>, Miera O.<sup>1</sup>, Cho M.-Y.<sup>2</sup>, Sinzobahamvya N.<sup>2</sup>, Berger F.<sup>1</sup>, Sigler M.<sup>4</sup>, Ovroutski S.<sup>2</sup>, Photiadis J.<sup>2</sup>

<sup>1</sup>German Heart Center Berlin, Department of Congenital Heart Disease – Pediatric Cardiology, <sup>2</sup>German Heart Center Berlin, Department of Congenital Heart Surgery – Pediatric Heart Surgery, <sup>3</sup>Charité-Universitätsmedizin Berlin, Institute for Cardiovascular Computer-assisted Medicine, <sup>4</sup>Georg-August University, Department of Pediatric Cardiology, Göttingen, Germany

### Objectives

The optimal material for aortic valve repair (AVR) has yet to be found. In this study we report our experience of AVR in congenital heart surgery (CHS) using CardioCel® patch material.

### Methods

In this retrospective study we reviewed data of 40 consecutive patients who underwent AVR using CardioCel® patch (Admedus Regen Pty Ltd, Perth, WA, Australia) between February 2014 and August 2016. Median age at operation was 9 (2-34 years), 26 patients presented initially with aortic valve insufficiency (AI) and 14 with stenosis (AS). For a median postoperative follow-up (FU) of 22 (6-42) months until August 2017, clinical and echocardiographic data was included. In case of reoperation, explanted CardioCel® patch material was examined histologically. Besides standard histological staining, Kossa stain (for identification of calcifications) and immunohistochemical staining was applied with antibodies specific for muscular, inflammatory, and connective tissue component antigens.

### Results

9/40 patients (23%) suffered from an adverse event during FU (death: n=1, 2.5%; re-operation: n=8, 20%). Overall, the probability of freedom from re-operation/death was 100%, 89%±6% and 56%±12% at median 10, 20 and 30 months FU (Fig. 1, A). Reason for re-operation was insufficiency in 4 patients (10%), stenosis in 3 patients (8%) and 1 patient (2.5%) was diagnosed with aortic valve endocarditis. 2 out of the remaining 31 patients are scheduled for re-operation (AS: n=1, AI: n=1) and 9 patients show decrease of aortic valve function with moderate AI. Freedom from developing combined endpoint (death/re-operation/moderate degree of aortic valve dysfunction (AS, AI)) after AVR was 97%±2.5%, 73%±8% and 33%±9% at 10, 20 and 30 months, respectively (Fig. 1, B). In echocardiography the patches appeared hyperechoic and thickened as they did macroscopically when explanted, presenting a thick neointima (Fig. 2). Histologically, all specimen (8/8 =100%) showed tissue proliferation and 50% showed inflammatory cell infiltration. 6 of 8 samples with implant times of 23 to 29 months revealed low-grade calcifications and only the two specimen with “short” implant times of 11 and 20 months showed no calcifications (Fig. 3).

### Conclusions

- AVR using CardioCel® pericardial patch material in patients with congenital aortic valve disease shows unsatisfactory results at 30 months FU.
- Explanted CardioCel® patches demonstrated proliferations and calcifications as possible reasons for patch performance failure.

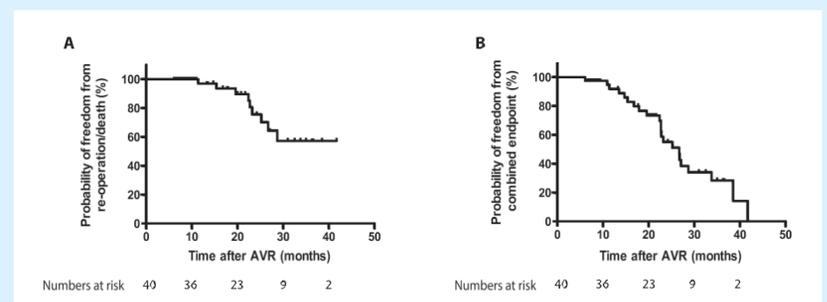


Figure 1: Kaplan-Meier survival analysis (initially 40 patients)



Figure 2: A) Explanted CardioCel® patch B) Thickened hyperechoic augmented cusp

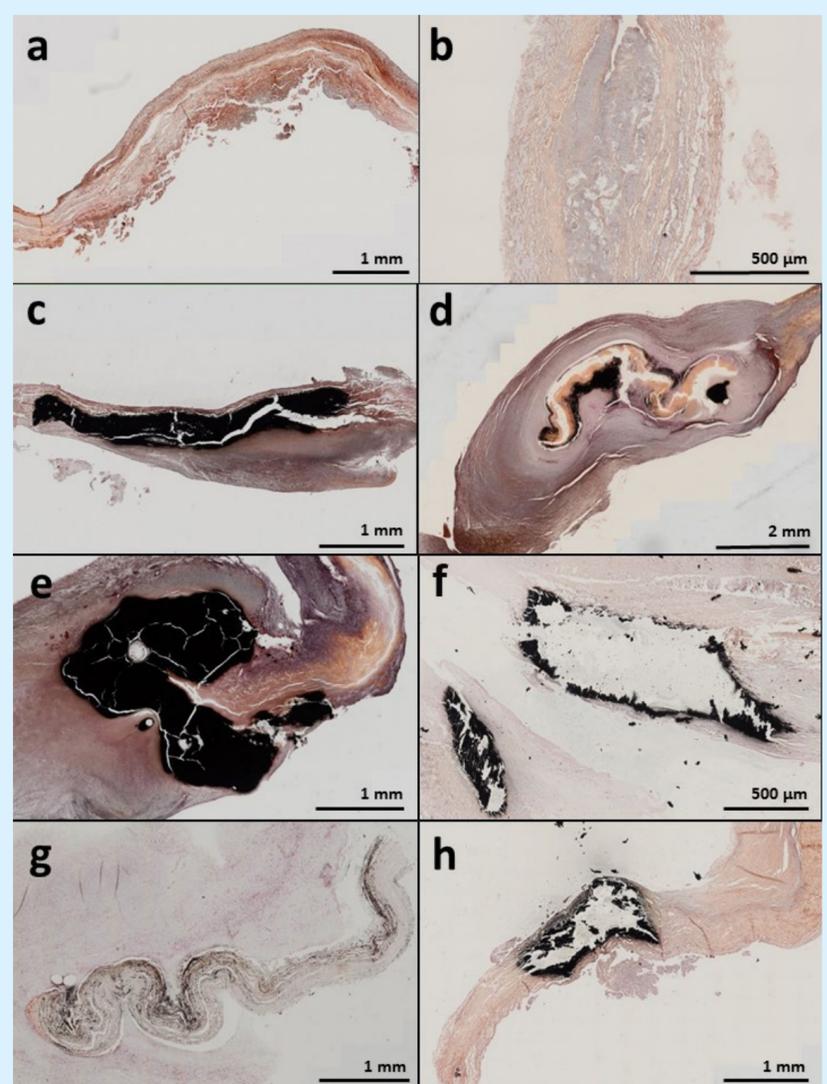


Figure 3: Explanted CardioCel® patches, Kossa stain counterstained with hemalaun (black = calcification)